

REMARKS

Reconsideration is respectfully requested. Claims 1, 4, 6, 9, 10, 16, and 18-23 are pending. Claims 2, 3, 5, 7, 8, 11-15, and 17 have been canceled. Claims 1, 4-6, 10, 19, and 20 are amended. No new matters have been added due to the amendments. Amendment to and cancellation of the claims does not affect inventorship.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Amendment

Claims 1, 10, and 20 are amended. Support is found, for example, in paragraph [0082]. Claims 6, 16, and 19 are amended to correct informalities.

Objections to the Specification

The Examiner maintains the objection of the Abstract and states that no amendment or argument of the Abstract was disclosed in the Argument/Remark filed on July 05, 2006.

Applicants respectfully submit that the Abstract was amended in the response dated June 30, 2006, at page 2, and remarks were presented on page 8. As such, Applicants respectfully request the objection on this basis be withdrawn.

Claims Rejections - 35 U.S.C. § 112, First Paragraph

As a preliminary matter, Applicants note that the Examiner maintain the rejections raised in previous Office Action, where the Examiner states that:

In general, for species of crystals to be adequately structurally described, the following must be adequately disclosed: (1) the composition of the crystal (exact structural features of all molecules in the crystal must be described, including the protein (preferably a SEQ ID NO of all included residues) and any molecule bound to it), (2) the space group, and (3) the unit cell dimensions of the crystal.

Applicants take issue with such statement. First of all, the pending claims are directed to genus of proteins in crystalline form, not species of crystals. Further, Applicants submit that "crystal" by itself

is a distinguishable structure feature. The space group and unit cell dimensions are not necessary to describe a protein in crystalline form.

I. Written Description

Claims 1, 4-6, and 9-10, 16-23 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Applicants respectfully traverse.

Claims 5 and 17 have been canceled, rendering the rejections moot.

With regards to claims 1, 10 and 20, the claims have been amended to recite the space group and unit cell, and as such, Applicants believe the rejections under 112, first paragraph for lacking written description and enablement should be withdrawn.

A. As regards claims 6, 16, and 19 (and claims dependent therefrom), the application meets the written description requirement because the application is sufficient to show that the inventor possessed the claimed invention.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. M.P.E.P. § 2163.

The instant application discloses that Applicants have conducted systematic screening to test numerous crystallization conditions and have produced numerous IspA crystals:

[S]ystematic broad screen crystallization trials were performed on an IspA complex using the sitting drop technique. Over 1000 individual trials were performed in which pH, temperature and precipitants were varied. In each experiment, a 100nL mixture of IspA complex and precipitant was placed on a platform positioned over a well containing 100µL of the precipitating solution. Precipitate and crystal formation was detected in the sitting drops. Fine screening was then carried out for those crystallization conditions that appeared to produce precipitate and/or crystal in the drops.

Based on the crystallization experiments that were performed, a thorough understanding of how different crystallization conditions affect IspA crystallization was obtained. Based on this understanding, a series of crystallization conditions were identified that may be used to form crystals comprising IspA. These conditions are summarized in Table 8.

Paragraphs [0086] and [0087].

Thus, the instant application not only describes methods to obtain claimed crystals and a series of crystallization conditions as shown in Table 8 in page 20, but also describes numerous crystals obtained

under those conditions. Out of these numerous crystals, the inventors picked one condition to pursue; clearly, the inventors made a wide variety of crystals under a variety of conditions. The chosen crystal is described in detail in Example 2. The instant application further discloses additional crystals could be produced used the disclosed methods and conditions:

[V]ariations on the crystallization conditions described herein can be readily determined by taking the conditions provided in Table 8 and performing fine screens around those conditions by varying the type and concentration of the components in order to determine additional suitable conditions for crystallizing IspA, variants of IspA, and ligand complexes thereof.

Paragraph [0088].

Accordingly, the Applicants present methods and numerous conditions to obtain the claimed crystals as well as numerous crystals produced using claimed methods. In view of the science and the teaching in the specification, Applicants submit that the instant application provides sufficient disclosure such that a person of skill in the art knows that the inventor possessed the invention including sufficient variations of the disclosed species to support the presently claimed genus. The Applicants further submit that a person of skill in the art of producing protein crystals would be well versed in using the claimed methods to produce claimed crystals under the guidance of the instant application, and Faulkner dictates a finding of adequate written description.

Finally, the Applicants submit that these arguments address the new § 112, first paragraph rejections.

II. Enablement

Claims 1, 4-6, and 9-10, 16 -23 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Specifically, the Examiner alleges that the specification fails to enable all crystals and methods as broadly encompassed by the claims. Applicants respectfully traverse.

Claims 5 and 17 have been canceled, rendering the rejections moot.

With regards to claims 1, 10, and 20, the claims have been amended to recite the space group and unit cell, and as such, Applicants believe the rejections under 112, first paragraph for lacking written description and enablement should be withdrawn.

With regard to claims 6, 16 and 19 (and claims dependent therefrom), the Examiner is respectfully reminded that the enablement requirement is met if the description enables any mode of making and using the invention. Moreover, a considerable amount of experimentation is permissible, if it

is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. *Johns Hopkins Univ. v. Cellpro, Inc.*, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998) (citations omitted). Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue experimentation. M.P.E.P. § 2164.01.

As argued above, the specification discloses a variety of crystals, formed under a variety of conditions. The fact that the inventor's chose only one of the crystals to move forward for further analysis, does not negate the existence of the other crystals. Accordingly, Applicants argue the enablement requirement is met.

In addition, as outlined above, a person of skill in the art of producing crystals would be well versed in using the claimed methods to produce claimed crystals under the guidance of the instant application. Applicants also point out that there is no need to test different conditions to obtain the optimal parameters in order to produce new crystals within the scope of the claim. Instead, generating additional crystals is well within the ability of one of skill in the art purely through using the disclosed methods as the instant application discloses a range of conditions for growing crystals. For example, the instant application discloses that:

Crystals comprising IspA may be formed by a variety of different methods known in the art. For example, crystallizations may be performed by batch, dialysis, and vapor diffusion (sitting drop and hanging drop) methods. A detailed description of basic protein crystallization setups may be found in McRee, D. and David. P., Practical Protein Crystallography, 2nd Ed. (1999), Academic Press Inc. Further descriptions regarding performing crystallization experiments are provided in Stevens, et al. (2000) *Curr. Opin. Struct. Biol.*: 10(5):558-63, and U.S. Patent Nos. 6,296,673, 5,419,278, and 5,096, 676. Paragraph [0083].

Given the absence of the need to perform any further screening to obtain optimal conditions for crystal growing, no undue experimentation is required to enable one of ordinary skill in the art to enjoy the fullest scope of the claimed invention. The Examiner's attention is again respectfully drawn to *Faulkner v. Inglis*, 79 USPQ2d 1001 (Fed. Cir. 2006), in which the Federal Circuit held that "[a] claim

will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language.”

Finally, the Applicants submit that these arguments address the new § 112, first paragraph rejections.

Accordingly, Applicants submit that the instant application reasonably provides enablement for making the crystals as encompassed by the claims. As such, the rejection based on this ground is improper and should be withdrawn.

New Rejections

Claims 16 and 19 are newly rejected under 35 U.S.C. §112, first paragraph, for a lack of written description. Claims 17-18 and 20-23 are newly rejected under 35 U.S.C. §112, first paragraph, for a lack of written description. Claims 16-19 and 20-23 are newly rejected under 35 U.S.C. §112, first paragraph, for a lack of enablement.

Applicants have addressed these rejections above.

CONCLUSION

Applicants respectfully submit that the claims are now in condition for allowance and early notification to that effect is respectfully requested. If the Examiner feels there are further unresolved issues, the Examiner is respectfully requested to phone the undersigned at (415) 442-1000.

Respectfully submitted,

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